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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/050,847	01/18/2002	Norman G. Anderson	2316-152	3042

7590 09/08/2004

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EXAMINER	
BURKHART, MICHAEL D	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 09/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/050,847	ANDERSON ET AL.	
	Examiner	Art Unit	
	Michael D. Burkhart	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-82* is/are pending in the application.

4a) Of the above claim(s) *1-60,62-63,72-73,78-79* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *61,64-71,74-77 and 80-82* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 January 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/18/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of group IV (claims 61, 64-71, 74-77, and 80-82) in the reply filed on 7/16/2004 is acknowledged. The traversal is on the ground(s) that the non-elected claims are related to the same type of microbanding tubes found in the elected claims. This is not found persuasive because, although all of the groups involve microbanding tubes, each is a distinct invention capable of supporting a separate patent for reasons stated in the restriction requirement. The tubes of group I and methods of groups II-IV are related as product and process of use, but the tubes can be used in materially different methods (i.e. any one of groups II-IV, plasmid DNA purification, etc.) and therefore are distinct. Groups II-IV are distinct inventions because each comprises steps and effects not found in the other groups: the dyes of group II, restriction endonucleases of group III and antibodies of group IV are not found in the other groups. The effects of the methods are also different: virus genome classification (group II), microorganism identification by restriction fragment analysis (group III), and microorganism identification by antibody reactivity (group IV). Therefore, a search of all the inventions would be burdensome.

The requirement is still deemed proper and is therefore made FINAL.

Priority

This application, 10/050,847, filed 1/18/2002, is a DIV of 09/571,279, filed 5/16/2000 (now US Patent 6,479,239, issued 11/12/2002) which is a DIV of 09/265,541, filed 3/9/1999

(now US Patent 6,254,834, issued 7/3/2001) which claims benefit of provisional application 60/077,472, filed 3/10/1998. The invention is granted a priority date of 3/10/1998.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 61, 64-71, 74-77, and 80-82 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 61, 64-71, 74-77, and 80-82 recite the use of antibodies for detection of microorganisms, wherein the antibodies are detectable by their fluorescence. Since natural antibodies are not fluorescent, it is unclear how applicants can detect said antibodies by fluorescence.

Claims 64, 68, 74, and 80 recite the limitation "fluorescent antibodies" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claims 64, 68, 74, and 80 recite the limitation "antibody-microorgansim conjugate band" in line 4. There is insufficient antecedent basis for this limitation in the claim.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 61, 64-71, 74-77 and 80-82 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants claim methods to identify a microorganism by concentrating said microorganism via ultracentrifugation, then incubating the concentrated microorganism with antibodies specific for known microorganisms. Applicants disclose methods to concentrate microorganisms by ultracentrifugation. The claims read on a genus of methods using an unknowable number of distinct antibodies to identify any microorganism known to science.

The written description requirement for a genus may be satisfied by sufficient description of a representative number of species by actual reduction to practice or by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between structure and function, or by a combination of such identifying characteristics, sufficient to show that applicant was in possession of the claimed invention. In the instant case, applicants only disclose methods necessary to concentrate microorganisms by ultracentrifugation and identify the protein content by MALDI-TOF analysis. Neither applicants nor the prior art disclose the method steps or antibody reagents necessary to practice the claimed methods. Each method claimed would require a unique antibody specific for a microorganism: by applicants own admission, "Hundreds of infectious agents are known, and it is infeasible to have available reagents for an appreciable fraction of them" (page 2 of the specification) and " These studies...require batteries of specific

antibodies..." (page 3 of the specification). Applicants claim the process of using antibodies to identify concentrated microorganisms by function only, without a correlation between structure and function. Applicants provide no disclosure of what antibodies and microorganisms might be involved, nor what conditions are suitable. Since the claims encompass potentially an unlimited number of microorganisms, each with a specific antibody for detection, it must be considered that these required reagents would vary greatly. Hence, the disclosure of no such antibodies would require the skilled artisan to conclude that the examples presented by the applicants are not sufficient to describe the claimed genus.

Claims 61, 64-71, 74-77 and 80-82 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The test of enablement is whether one skilled in the art could make and use the claimed invention from the disclosures in the application coupled with information known in the art without undue experimentation (*United States v. Telectronics,* Inc. 8 USPQD2d 1217 (Fed. Cir. 1988)). Whether undue experimentation is required is a conclusion reached by weighing several factors. These factors were outlined in *Ex parte Forman,* 230 USPQ 546 (Bd. Pat. App. & Inter. 1986) and again in *In re Wands,* 8 USPQQ2d 1400 (Fed. Cir. 1988) and include the following:

Unpredictability of the art. The art concerning production and use of antibodies to detect specific microorganisms in specific assays is unpredictable. Because some antibodies work well in some immunoassays (such as ELISA), but not in others (western blotting), it is not predictable

that simply raising antibodies to an organism would satisfy the requirements of the claimed methods. For example, the antibody/antigen interaction is sometimes sensitive to increasing ionic strength, yet applicants propose to bind antibodies to microorganisms within the density gradient solutions: high ionic strength solutions that typically consist of 5-50% sucrose or 1.5 - 8.0 M cesium chloride. See, for example Hayrinen et al. (Mol. Immun.; 39 p.399-411: 2002) and Takeda et al.(Lupus; 10 p.857-865: 2001) establishing that the avidity of some antibodies for antigen decreases with increasing ionic strength.

State of the art. The state of the art regarding the production of antibodies that will function under the claimed conditions (high ionic strength), is poorly developed. The development of such antibodies would have to be done empirically, along with the development of the appropriate method steps concerning their use as claimed.

Number of working examples. Applicants have provided no working examples of identification of microorganisms by ultracentrifugation and incubation with an antibody specific for a microorganism.

Amount of guidance. Applicants provide no direction for the acquisition or production of the required antibodies, nor the necessary steps for their use. The specification requires the skilled artisan to practice trial and error experimentation to produce highly specific antibodies and to develop method steps for their use as claimed.

Scope of the invention. The claims are extremely broad in nature and read on any microorganism and antibodies specific to said microorganism.

Nature of the invention. The invention involves the unpredictable art of producing antibodies that will function in a specific assay, under high ionic strength.

Level of skill in the art. While the level of skill in the art is high, the unpredictability of the art, lack of guidance, broad scope of the claims and poorly developed state of the art would require that undue and excessive experimentation would have to be conducted by the skilled artisan in order to practice the claimed invention.

Given the above analysis of the factors which the courts have determined are critical in determining whether a claimed invention is enabled, it must be considered that undue and excessive experimentation would have to be conducted by the skilled artisan in order to practice the claimed invention.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael D. Burkhart whose telephone number is (571) 272-2915. The examiner can normally be reached on M-F 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael D. Burkhart
Examiner
Art Unit 1636

DAVID GUZO
PRIMARY EXAMINER